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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,457	11/29/2000	Meir Shinitzky	24390	6935

20529 7590 04/07/2004

NATH & ASSOCIATES  
1030 15th STREET  
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WASHINGTON, DC 20005

EXAMINER

TURNER, SHARON L

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/647,457	SHINITZKY ET AL.	
	Examiner	Art Unit	
	Sharon L. Turner	1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,7,8,11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☒ Claim(s) 3,7,8,11,13 and 14 is/are objected to.
- 8) ☒ Claim(s) 1,3,7,8,11,13 and 14 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims withdrawn from consideration are claim 1 and claims 3, 7-8, 11, and 13-14 to the extent drawn to sequences other than SEQ ID NO:3.

**Response to Amendment**

1. The amendment filed 1-9-04 has been entered into the record and has been fully considered.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of Applicant's amendment, all rejections not reiterated herein have been withdrawn by the examiner.
4. Claims 1, 3, 7-8, 11, and 13-14 are pending.

***Election/Restriction***

5. Applicant's election with traverse of Group I, claims 1-6, 8, 10-11 and 13-14 in part to the extent drawn to the technical feature of SEQ ID NO:2 in Paper No. 10 (4-29-02) is acknowledged. It is noted that claims 7 and 12 have now been presented as a part of the invention of Group I, drawn to SEQ ID NO:2. The traversal is on the ground(s) that there is no appropriate explanation of serious burden. Applicants submit that there is no serious burden because a search of any one of the inventions would require searching areas appropriate to the other inventions and further because Applicants would be forced to pay further fees for search and examination of the additional inventions. This is not found persuasive because as previously set forth the technical features differ in sequence structure, function, effects and are capable of distinct utilities. There is extensive search burden in examining all the inventions in a single application because the search for any one group is not co-extensive with a search for any other group, in particular the sequence searches are different for each

invention. The fee structure has been determined by the Office to be appropriate compensation for the burden of search and examination of alternative inventions.

The requirement is still deemed proper and is therefore made FINAL.

6. It is noted for the record that original SEQ ID NO:2 is now SEQ ID NO:3 as amended by the new CRF and Sequence listing, see amendments of 9-16-03 and 1-9-04.

7. Newly submitted claim 1 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The new sequence identifier and noted generic sequence of claim 1 do not apparently correspond to a generic sequence that represents elected SEQ ID NO:3 or that is supported within the specification as originally filed. For example, the sequence of SEQ ID NO:1 is apparently anticipated by Hedges et al., PNAS 91:2621-24, 1994, see in particular attached alignment. Since applicant has received an action on the merits for the originally presented invention (SEQ ID NO:3), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 1 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 3, 7-8, 11, 13-14 to the extent of SEQ ID NO:3 will be examined as drawn to the elected invention. It is noted that SEQ ID NO:1 is not generic to SEQ ID NO:3 as specified in either the sequence listing or claim.

8. This application contains generic claim 1, from which all claims depend, and claims 3, 7-8, 11 and 13-14 drawn to an invention nonelected with traverse in Paper No.

10. A complete reply to the final rejection must include cancellation of nonelected

claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. It is further noted that the generic claim is not apparently drawn to or representative of elected SEQ ID NO:3.

9. Claims 3, 7-8, 11, 13-14 are objected to as being drawn to a non-elected invention, (as reciting an improper Markush Group and/or inventions that are non-linking). M.P.E.P. 803.02 states that:

“Since the decisions in *In re Weber* \*\*, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

In particular it is noted that the additional sequences within claims 3 and 11 to which all claims are drawn lack a common core structure and thus remain drawn to non-elected inventions. None of the representative sequences is generic or shared with elected SEQ ID NO:3.

10. Claims 3, 7-8, 11 and 13-14 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As previously noted SEQ ID NO:1 is not apparently generic to elected SEQ ID NO:3.

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Moreover, the dependent claims do not apparently further limit claim 1.

### ***Specification***

11. The amendments filed 9-16-03 and 1-9-04 are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Those changes that are newly drawn to a generic sequence represented as new SEQ ID NO:1 within the sequence listing. The sequence represented is not apparently supported by the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Status of Claims***

12. No claims are allowed.

### ***Allowable Subject Matter***

13. Peptides consisting of or comprising SEQ ID NO:3 are free of the prior art of record, as previously noted. Claims directed to such subject matter would be allowable if so presented.

### ***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
April 2, 2004

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**